

)	MDL No. 1456
In re: PHARMACEUTICAL INDUSTRY)	Master File No. 01-12257-PBS
AVERAGE WHOLESALE PRICE LITIGATION)	Subcategory Case No. 06-11337
)	
)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO:)	
)	
<i>State of California ex rel. Ven-A-Care of the Florida</i>)	
<i>Keys, Inc. v. Abbott Labs, Inc. et al.,</i>)	
Civil Action No. 03-11226-PBS)	
)	

Pursuant to Local Rule 56.1, Defendant Sandoz Inc. (“Sandoz”) presents this statement of material facts as to which there is no genuine issue to be tried in support of its Motion for Summary Judgment.

2. Pursuant to the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990), manufacturers of prescription drugs, including Sandoz, which seek to participate in the Medicaid program under Title XIX of the Social Security Act for provision of outpatient drugs are required to enter into a rebate agreement with the Secretary of Health and Human Services. See 42 U.S.C.A. § 1396r-8 (2009).

3. Effective January 1, 1991, Sandoz entered into such a rebate agreement with the Secretary of Health and Human Services. See Rebate Agreement Between The Secretary of Health and Human Services and Sandoz Inc. date stamped March 5, 1991 (hereinafter the “Rebate Agreement”), attached to the Declaration of Catherine Castaldo (hereinafter “Castaldo Decl.”) as Ex. A. The Rebate Agreement remained in effect and did not substantially change from January 1, 1994 to December 31, 2004 (the “Relevant Time Period”).

4. The Rebate Agreement required Sandoz to, among other things, furnish certain information to the Secretary of Health and Human Services, including data regarding Average Manufacturer Price (“AMP”). See Castaldo Decl. Ex. A. at II(e).

5. The Rebate Agreement defines AMP as “the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail class of trade.” See Castaldo Decl. Ex. A. at I(a).

6. The Rebate Agreement states that AMP “includes cash discounts allowed and all other price reductions.” See Castaldo Decl. Ex. A at I(a).

7. The State of California considered AMP to be a more accurate reflection of transaction prices for drugs than Average Wholesale Price (“AWP”) and other pricing indicators.

Castaldo Decl. Ex. B. (Transcript of Deposition of Mike Namba (“Namba Tr.”) 150:5 – 10, Apr. 23, 2009)

Q: Now, have – would you agree that Average Manufacturer Price more closely approximates Average Acquisition Cost as compared to AWP?

A: I believe so.

Castaldo Decl. Ex. C. (Transcript of Deposition of Vic Walker (“Walker Tr.”) 161:22162:4, May 21, 2009).

Q: Okay. Would you consider AMP to be a better estimate of acquisition cost?

A: Better than what?

Q: AWP?

A: Probably.

Castaldo Decl. Ex. D. (Transcript of Deposition of Roy Takeuchi (“Takeuchi Tr.”) 146:2 – 13, June 10, 2009).

Q: Okay. And is that consistent with your understanding that AMP was a more accurate price?

A: Is it a more accurate pricing? Well, I always thought that. I’m not really sure. I think that’s what it was.

Q: In your mind AMP was a more accurate price than other prices available?

A: I think that’s what was considered, yes.

8. Pursuant to its obligations under the Rebate Agreement, the Secretary of Health and Human Services, through CMS, is required to provide participating State Medicaid Agencies, including California, Unit Rebate Amounts (URA), which the states then use to invoice manufacturers for the rebates owed. See 42 U.S.C.A. § 1396r-8 (2009); Castaldo Decl. Ex. E. (Letter from Lori A. Ahlstrand, Regional Inspector for Audit Services, Dept. of Health and Human Services to Diane Bonta, Director, California Dept. of Health Services, enclosing 2003 Office of Inspector General Report: Audit of the Medicaid Drug Rebate Program in California, dated Dec. 23, 2003 (CAAG/DHS-E0032592 – E0032610)); see also

Castaldo Decl. Ex. F. (Transcript of Deposition of Kevin Gorospe (“Gorospe Tr.”), 713:16 – 714:11, Sept. 22, 2008)

Q: Okay. And correct me if I’m wrong, but every quarter CMS or HCFA, when HCFA was the name of the agency, sends Medi-Cal a list of what’s called the unit rebate amount for each drug that California reimbursed for; isn’t that right?

A: Specifically they send a file with a unit rebate amounts for all NDCs as reported to them by manufacturers, whether or not California reimbursed the product.

Q: Oh, okay. And do you have access to that entire list?

A: Yes. Q: Okay. So whether or not were reimbursed for a particular drug, you can actually look at the URA for that drug?

A: If it was reported by the manufacturer, correct.

Castaldo Decl. Ex. G. (Transcript of Deposition of Deidre Duzor (“Duzor Tr.”), 674:14-22, Mar. 26, 2008)

Q Okay. CMS calculates the URA and it sends the URA to all the states, right?

A: Yes.

Q: And each state gets URAs for all the drugs that it reimburses for?

A: Yes.

Q: And it gets those URAs, again, by NDC number?

A: Yes.

9. From January 1, 1991 to December 31, 1993, URAs were set at 10% of AMP. From January 1, 1994 onwards, URAs were set at 11% of AMP. See 42 U.S.C. § 1396r-8(c)(3)(B)(2009). To calculate AMP from URA, one simply had to divide the URA amount by .1 (from 1991 to 1993) and .11 (from 1994 onwards); see also

Castaldo Decl. Ex. H. (Transcript of Deposition of Larry Reed (“Reed Tr.”), 1319:6 – 1321:3, Oct. 2, 2008)

Q: Okay, so in '91, '92, '93 they are getting URAs that at 10 percent of the AMP, correct?

A: Correct.

Q: So the state Medicaid person who got URAs during that time period could look at that URA and pretty much know exactly what the AMP is just by moving the decimal point one place, correct?

Q: True?

A: There would be a way to figure – probably a way – 10 percent would be 10 percent of AMP, so basically that’s correct.

Q: So really it’s not much of a calculation, you just have to move the decimal point, right?

A: It would be 10 percent.

Q: It would be a pretty easy calculation, correct?

A: Again, if it was 10 percent it would be 10 times that amount.

Q: Now, the next year it went to 11 percent, correct?

A: In the calendar year 1994.

Q: And it's been at 11 percent ever since, correct?

A: Correct.

Q: So again, anyone in the state Medicaid office who gets the URA for – the URAs for generic drugs can, by doing a simple mathematical computation based on 11 percent, pretty readily determine what the AMP is, correct?

A: Correct.

Castaldo Decl. Ex. G. (Duzor Tr. at 679: 12-21)

Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right? A: Yes. The AMPs have been fairly transparent for generic drugs. Q: If you have the URA? A: Because – right, because of the simple formula.”

10. Armed with URAs, the State of California can easily determine the AMP for a given drug.

Castaldo Decl. Ex. I. (Transcript of Deposition of Kevin Gorospe (“Gorospe Tr.”), 77:9-16, Mar. 19, 2008)

Q. So it if was ten percent -- if the rebate was ten percent of AMP and you -- all you would have to do is sort of, you know, use simple division to figure out what the AMP was based on the unit rebate amount?

A: Correct.

Castaldo Decl. Ex. J. (Transcript of Deposition of Craig Miller (“Miller Tr.”), 83:15 – 84:8 Sept. 24, 2008)

Q: But that's something you could fairly -- at least for the noninnovator multiple source drugs we talked about a few minutes ago, that's something that if I -- if you wanted to you could figure that AMP number relatively simply; couldn't you? ...

A: Oh. Yes.

Q: I mean you just do the math?

A: Right.

Q: You reverse that division –

A: Right.

Q: -- with a calculator, and you've got the AMP?

A: Right.

Castaldo Decl. Ex. K. (Transcript of Deposition for Douglas Hillblom (“Hillblom Tr.”) 264: 17-19, Sept. 23, 2008)

Q: How would you derive AMP from URA?

A: You'd have to take the URA amount and divide it by the appropriate percentage, and multiply it by a hundred.

11. The State of California has used URA information to calculate manufacturers' AMP data.

Castaldo Decl. Ex. B. (Namba Tr. at 165:14-166:5)

Q: And what information did you have about the -- in connection with the CMS rebate? Is this -- did you have AMPs, or did you have URAs? Do you recall?

A: Yes. If the manufacturer had contacted us and was interested in pursuing additional formulary, they'd give us AMP. That was the requirement. So we had it. But we could also calculate from the CMS information that we had, because our rebate was set at 11 percent fixed.

Castaldo Decl. Ex.B. (Namba Tr. at 166:16 -- 167:3)

Q: Okay. But ... you just noted that you could find -- from the unit rebate amount you could -- you could calculate the -- what the AMP would be?

A: For generic drugs.

Q: For generic drugs right. And so you saw, when you calculated AMP for the generic drug, that it -- it was a very low number; right?

A: Correct.

12. Notwithstanding its obligations to provide AMP data to the federal government pursuant to the Rebate Agreement, beginning on July 16, 1991, Sandoz voluntarily provided the State of California with its AMP data. See Castaldo Decl. Ex. L. (Letter from Beth Brannan, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to Michael Neff, California Dept. of Health Services enclosing AMP data, dated July 16, 1991 (SANDOZ CALI 3000033)); see also

Castaldo Decl. Ex. D. (Takeuchi Tr. at 145:3 -22)

Q: Mr. Takeuchi, -- based on Exhibit 17 through 19 would you agree with me that California received Sandoz' AMPs for its products reimbursed by California.

A: Just what I see, it looks like it.

Q: Okay.

A: I don't know if that's everything.

Q: But California did receive AMPs for at least some products from Geneva from 1992 through 1996; correct?

A: If – if the mailing and everything else was correct, looks like it.

13. Sandoz continued to directly provide the State of California with its AMP data until March 21, 1997. See Castaldo Decl. Ex. M. (Letter from Ron Hartmann, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to State of California enclosing AMP data, dated Mar. 21, 2007 (SANDOZ CALI 3001109)).

Dated: November 25, 2009
New York, NY

Respectfully submitted,

WHITE & CASE LLP

/s/ Wayne A. Cross

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CERTIFICATE OF SERVICE

I, Jacqueline L. Chung, hereby certify that on November 25, 2009, I have caused true and correct copies of the foregoing Local Rule 56.1 Statement of Undisputed Facts in Support of Defendant Sandoz' Inc.'s Motion for Summary Judgment to be served on all counsel of record by electronic service, pursuant to the Case Management Order No. 2 entered in by Honorable Patti B. Saris in MDL 1456.

/s/ Jacqueline L. Chung
Jacqueline L. Chung